

Summary of Key Conformity Assessment Activities and Examples of U.S. Programs

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PPT Conformity Assessment
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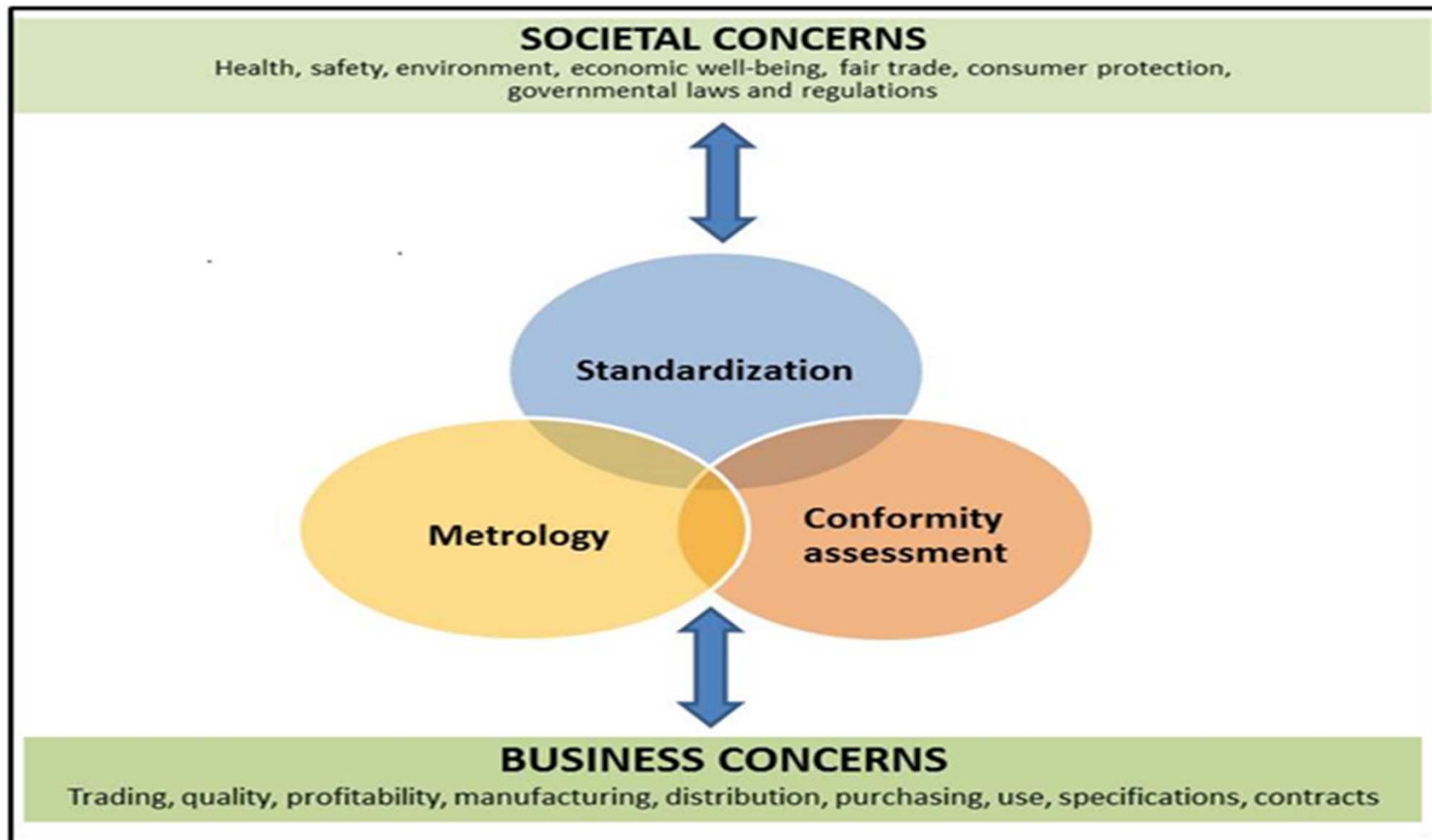
Conformity Assessment

“Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled” ISO/IEC 17000:2004

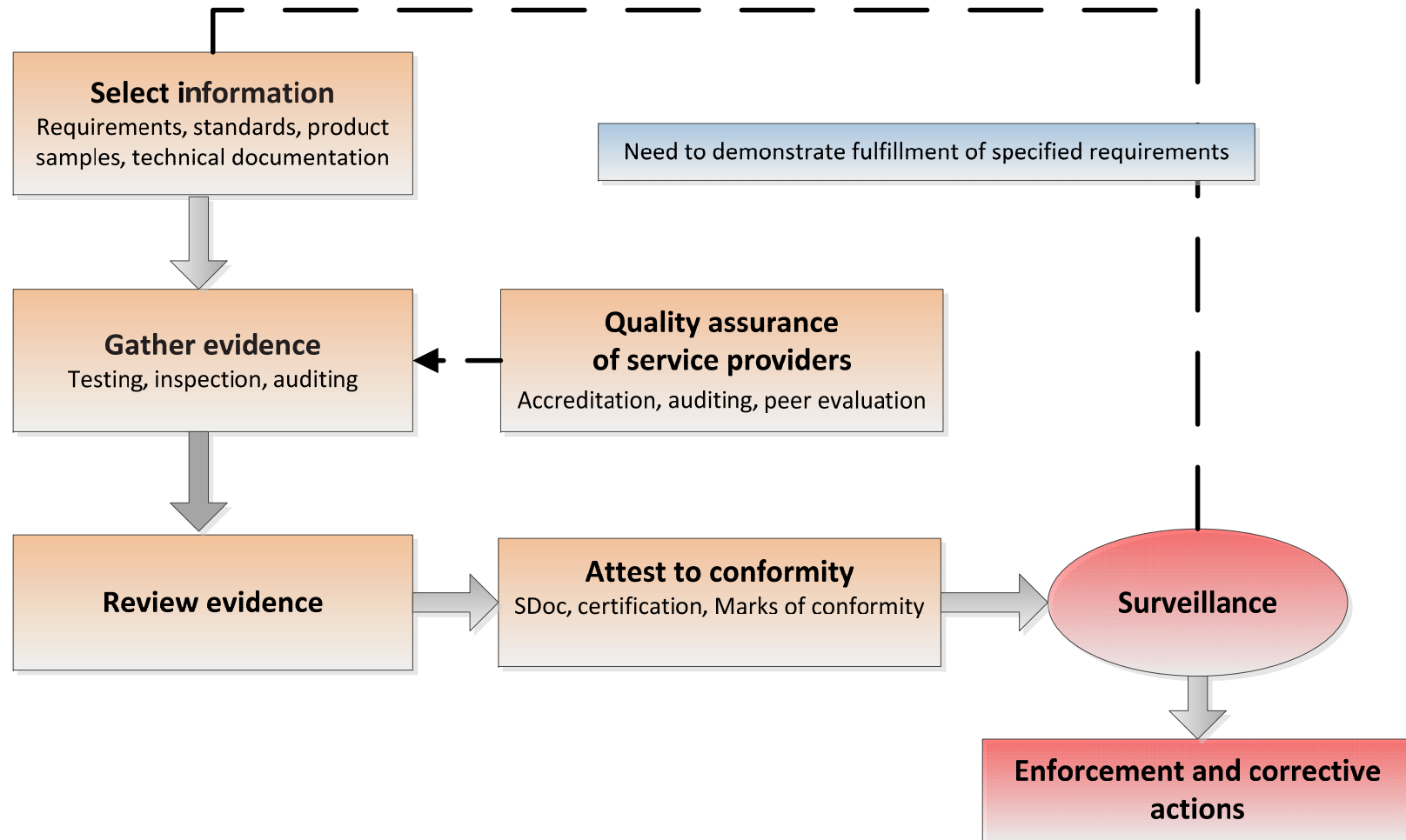
Conformity assessment Vocabulary and general principles

- Provide consumers with added confidence
- Give the company a competitive edge
- Help regulators ensure that health, safety or environmental conditions are met

Conformity Assessment in a Quality Infrastructure



Functional Approach to Conformity Assessment



ISO Conformity Assessment

Committee on Conformity Assessment (CASCO)

- ▶ **Develops policy and publishes standards**
 - **Promote mutual recognition and acceptance of national and regional conformity assessment systems, and the appropriate use of International Standards for testing, inspection, certification, assessment and related purposes**
 - **Published 28 conformity assessment standards**
 - **Participating countries: 71 – ANSI is US representative**
 - **Observing countries: 48**

ISO Conformity Assessment

- ▶ **Main forms of conformity assessment**
 - Certification - ISO/IEC 17065 – 2012, Requirements for bodies certifying products, processes and services
 - Inspection - ISO/IEC 17020 – 2012, Requirements for the operation of various types of bodies performing inspection
 - Testing - ISO/IEC 17025 – 2005, General requirements for the competence of testing and calibration laboratories

ISO Conformity Assessment

- ▶ **Main forms of conformity assessment (cont.)**
 - Accreditation - ISO/IEC 17011- 2004, General requirements for accreditation bodies accrediting conformity assessment bodies
 - Surveillance - ISO/IEC 17011, ISO/IEC 17065
ISO/IEC 17020
 - Supplier's Declaration of Conformity - ISO/IEC 17050,
Part 1: General requirements
Part 2: Supporting documentation

ISO Conformity Assessment

- ▶ **Main forms of conformity assessment (cont.)**
 - Quality management systems - ISO/9001 – 2008
Requirements for a quality management system to demonstrate the ability to provide products that fulfill customer and applicable regulatory requirements
 - Registration - ISO/IEC 17021 – 2011, Requirements for bodies providing audit and certification of management systems

U.S. PPT Conformity Assessment

- ▶ A uniform comprehensive program does not exist
- ▶ Consensus standards do not typically contain CA requirements (ANSI, ASTM)
- ▶ OSHA basic health and safety requirements “incorporate by reference” U.S. consensus standards
- ▶ Consequently, supplier's declaration of conformity with no third-party verification or follow-up market surveillance and enforcement is the norm

U.S. PPT Conformity Assessment

- ▶ **Current CA programs are product-directed and designed primarily for products that protect workers against serious (medium to high) hazards**
- ▶ **Consequently, both private and public sectors apply CA requirements in different ways to like hazard levels**

Examples:

- **NIOSH (respirators) and NIJ (bomb suits)**
- **NFPA (fire and emergency services products)**

42CFR84 NIOSH Respirator Conformity Assessment Activities

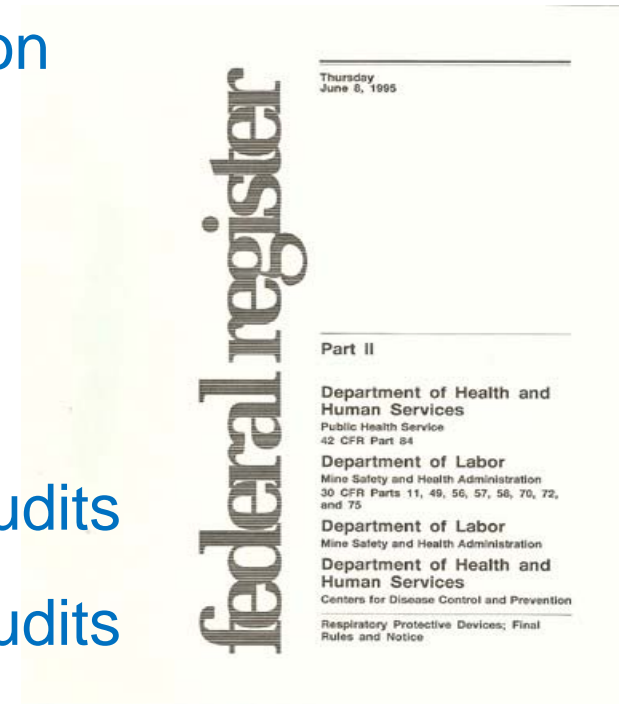
Certification Activities

- Engineering Evaluation
- Respirator Testing
- QA Plan Evaluation



Post Market Activities

- Manufacturing Site Audits
- Respirator Product Audits
- Respirator Evaluations



NIJ/DOJ/Office of Justice Programs Public Safety Bomb Suit

- ▶ **NIJ Standard – 0117.00 Public Safety Bomb Suit Standard, March 2012**
 - Voluntary performance standard providing for one level of protection
 - Defines both performance requirements and the methods used to test performance
 - “Incorporates by references” national and international standards (NFPA, MIL, ANSI, ASTM, EDA, IEC, CSA)

NIJ/DOJ/Office of Justice Programs Public Safety Bomb Suit

- ▶ **NIJ CR – 0117.00 Public Safety Bomb Suit Certification Program Requirements, March 2012**
 - Certification (ISO/IEC Guide 65) with additional NIJ requirements (e.g. surveillance frequencies, safety alerts, product recalls, independent third parties for testing and inspections)
 - Testing (ISO/IEC 17025)
 - Inspections (ISO/IEC 17020)
 - Quality management system (ISO 9001)
 - Registration (ISO/IEC 17021)

NFPA - Fire and Emergency Services Conformity Assessment

- ▶ ***13 PPT and PPE product standards apply Certification (Chapter 4) requirements***
 - Third-party certification (ISO/IEC 17065)
 - Notified body accreditation (ISO/IEC 17011)
 - Inspection and testing (ISO/IEC 17025)
 - Annual recertification
 - Manufacturer's quality assurance program (ISO-9001)
 - Registration (ISO/IEC 17021)
 - Investigation of hazards (ISO Guide 27)
 - Manufacturer's investigation of complaints and returns
 - Manufacturer safety alert and product recall systems

U.S. PPT Conformity Assessment

- ▶ Existing PPT CA programs in the U.S. represent a wide diversity of approaches
- ▶ Current requirements for pre-market CA and post market surveillance and enforcement varies across products intended for like levels of hazard
- ▶ Merger of private and public sector CA programs could form a national framework to deliver a uniform comprehensive program providing confidence in a standard level of protection for workers

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Thank you!